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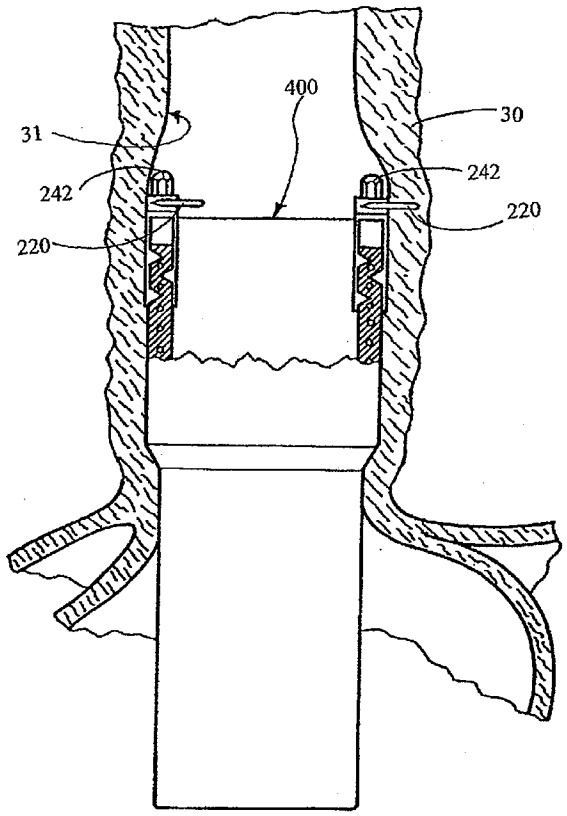
(54) **Title:** DEVICE FOR SECURING TO WALL OF INTERNAL LUMEN



(57) **Abstract:** An apparatus and method for securing medical devices to an internal wall (31) of a biological lumen. In one aspect the invention is an apparatus (400) to be inserted into a biological lumen having an internal wall (31), said apparatus (400) comprising a curved needle (220) pivotable about an axis between an open position and a closed position and adapted to pierce and engage said internal wall (31) when pivoted from said open position to said closed position.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE FOR SECURING TO WALL OF INTERNAL LUMEN

Field of the Invention

This invention relates generally to the field of internal medical devices, and specifically to methods and apparatus for securing medical devices to the internal wall of a biological lumen into which it has been inserted.

Background Art

Medical devices are inserted into biological lumens for a variety of reasons. For example, in the treatment of gastroesophageal reflux disease (GERD), a medical prosthesis, such as that shown in United States Patent 5,861,036, Godin, is inserted into the esophagus. In order to prevent gastric juices from refluxing into the esophagus and causing esophageal mucosal injury ("esophagitis"), the medical prosthesis must remain properly positioned within the esophagus.

Getting medical devices, such as a prosthesis used to treat GERD, to remain properly positioned within a body lumen for an extended period of time has proven to be a significant challenge in the medical field. While ensuring that the medical devices are properly sized has helped reduce the problem, it is still common for internal medical devices to shift and/or disengage from their proper position within the biological lumen despite proper sizing. Current methods for securing medical devices to the internal wall of the desired lumen include suturing, gluing, and using suction/aspiration. However, none of these techniques have proven to be satisfactory.

Glues, such as cyanacrylates, are commonly used to secure medical devices to the internal wall of the desired biological lumen by applying the glue to the exterior of the medical device and holding the device in contact with internal wall. Using glues presents a number of problems. First, glues dry very quickly and can result in the medical device prematurely bonding in an undesired orientation. Once adhered, glues are not easily reversible and further moving the medical device is difficult. Additionally, glues can cause problems when being handled with an endoscope. Often the endoscope or optics can end up being glued

to the medical device itself or the optics of the endoscope can be opacified by the glue itself.

Suturing is another method of securing medical devices to the internal wall of a biological lumen. Suturing is unsatisfactory in that space can be very limited within the lumen, causing the suturing job to be very difficult. This can result in the doctor obtaining a less than optimal suture.

Another method that exists for securing medical devices within the lumen is the use of aspiration/suction to induce a proturbence of the mucosa into a cavity of the medical device. Such a method is disclosed in United States Patent 6,285,897, Kilcoyne, which is hereby incorporated by reference. Suction has proven to be unsatisfactory in that the medical device will slough off with the mucosa in a matter of days and can not be used to secure the medical device to the internal wall for an extended duration.

Disclosure of the Invention

It is therefor an object of the present invention to provide a method and apparatus for insertion into a biological lumen that more securely engages an internal wall of the biological lumen.

Another object is to provide a method and apparatus for insertion into a biological lumen that can remain secured to the internal wall of the biological lumen for an extended period of time.

Yet another object is to provide a method and apparatus for insertion into a biological lumen that remains properly positioned.

A further object of the present invention is to provide a method and apparatus for insertion into a biological lumen that can be easily secured to the internal wall of the biological lumen.

A still further object is to provide a method and apparatus for insertion into a biological lumen that can be easily removed from the internal wall of the biological lumen after it is secured thereto.

Still another object is to provide a method and apparatus for insertion into a biological lumen that does not interfere with an endoscope or other optics while being secured to the internal wall.

These objects and others are met by the present invention, which in one aspect is an apparatus to be inserted into a biological lumen having an internal wall comprising a pivotable curved needle pierces and engages the internal wall when pivoted from an open position to a closed position. To remove or adjust the apparatus, the curved needle can be pivoted from the closed position back to the open position, to disengage the internal wall of the biological lumen.

The term biological lumen as used herein is meant to include body cavities and/or orifices. The biological lumen can be, for example, the stomach, colon, rectum, bladder, uterus, vagina, biliary ducts (including the common bile duct), or blood vessels. When the biological lumen is the esophagus, the apparatus will be an anti-reflux device, such as that disclosed in United States Patent 5,861,036 or United States Application Publication 2003/0009236, both of which are incorporated by reference herein. The term "esophagus" in this discussion includes the lower esophageal sphincter (LES).

It is preferred that the curved needle be pivotally mounted via a tight-fit assembly, for example, with a hub having a bottom surface with a cylindrical stub protruding therefrom, the cylindrical stub tightly fits into a corresponding cavity in the apparatus when it is inserted therein. It is also preferable to have the curved needle protrude from a side wall of the hub. While a tight fit assembly is preferred, any type of pivotal connecting means can be used, such as a bolt and nut, a screw, a rivet, a flange, or a ball bearing connection.

The curved needle is preferably substantially semi-circular shaped, which improves the ability of the needle to pierce and reliably engage the internal wall of the biological lumen. To easily pivot the curved needle, the hub preferably comprises a female socket or a bolt head to be engaged by a rotational tool. The rotational tool can be supplied via an endoscope.

It is preferable that the curved needle is pivotably mounted on a clip body. In order to avoid the needle being over-pivoted and possibly tearing through the membrane of the internal wall during engagement, the apparatus preferably has a stopper to prevent the curved needle from pivoting beyond the closed position when pivoted from the open position.

The clip body can comprise a cavity into which the cylindrical stub can be inserted to form a tight pivotal fit. The clip body can be a rigid structure comprising a front plate, back plate, and top plate. The top plate can have a hole and either or both of the front and back plates can have one or more teeth to secure the clip body to another element of the apparatus. A sleeve forming a cavity can be positioned between the front and back plates so that the hole and the sleeve cavity are substantially aligned. When a sleeve is used, the curved needle can be pivotally connected to the clip body by extending the cylindrical stub through the hole in the top plate and into the sleeve cavity to form a tight fit.

In another aspect, the invention comprises a method of securing an apparatus to an internal wall of a biological lumen with a pivotable curved needle having an open position and a closed position; inserting the apparatus into the lumen; and pivoting the curved needle about an axis to the closed position, thereby causing the curved needle to pierce and engage the internal wall. The curved needle can be in either the open or the closed position during the insertion of the apparatus.

The apparatus can be removed or adjusted by pivoting the curved needle about the axis from the closed position back to the open position, thereby causing the curved needle to disengage the internal wall.

Brief Description of the Drawings

Figure 1 is a side view of a balloon catheter positioned in an esophagus.

Figure 2 is a top perspective view of an embodiment of a clip assembly having a pivotable curved needle according to the present invention.

Figure 3 is an exploded view of the clip assembly embodiment of FIG. 2.

Figure 4 is a perspective view an endoscopic rotational tool about to engage the clip assembly connected to a section of a wall an anti-reflux prosthesis.

Figure 5 is a side, partially cut-away view of an anti-reflux prosthesis, partially in section, according to an embodiment of the present invention inserted within an esophagus, illustrated in cross-section

Figure 6 is a perspective view of an embodiment of a clip assembly according to the present invention with a female socket.

Modes for Carrying Out the Invention

Referring first to FIG. 1, a balloon catheter is inserted into esophagus **30** to determine the size of esophagus **30** and thereby the proper size of the ring of the anti-reflux prosthesis **400** (FIG. 5) for insertion. Balloon catheter **10** comprises balloon **11**, syringe **12** and pressure monitor **13** (illustrated as a generic box). In order to determine the diameter of the internal wall **31** of esophagus **30**, balloon **11** is inserted into esophagus **30** until it reaches the location to be sized. Once in position, balloon **11** is inflated by depressing plunger **14** of syringe **12** which is filled air, oxygen, or some other gas. Balloon **11** is inflated by syringe **12** until balloon **11** contacts internal wall **31** of esophagus **30**. Upon contacting internal wall **31** of esophagus **30**, an increase in pressure is detected by pressure monitor **13**. The volume of air supplied to balloon **11** by syringe **12** is recorded and correlated to a specific balloon diameter. This diameter is used to choose an appropriately sized anti-reflux prosthesis for insertion into esophagus **30**. Balloon **11** is deflated and removed from esophagus **30**.

Referring now to FIGS. 2 and 3, an embodiment of a clip assembly **200** comprises clip body **210**, curved needle **220**, stopper **230**, hub **240**, and sleeve **250**. Clip body **210** is a rigid structure and comprises top plate **211**, front plate **212**, and back plate **213**. Front plate 212 and back plate 213 have teeth **215**. Teeth **215** are adapted to secured clip assembly **200** to wall **610** (FIG. 4) of anti-reflux device **400** (FIG. 5) by either biting into wall **610** or fitting into corresponding indentations.

Referring to Fig. 3, curved needle **220** is substantially semi-circular shaped and protrudes from side wall **243** of hub **240**. Hub **240** also comprises cylindrical stub **241** protruding from its bottom. Sleeve **250** forms sleeve cavity **251**. Sleeve **250** is positioned between front plate **212** and back plate **213** so that sleeve cavity **251** is substantially aligned with hole **214** of top plate **211**. When assembled, cylindrical stub **241** extends through hole **214** of top plate **211** and into sleeve cavity **251** of sleeve **250**. Cylindrical stub **242** is sized and shaped to form a tight fight with sleeve cavity **251** while still allowing rotation/pivoting therewith. As such, curved needle **220** is pivotally connected to clip body **210**, allowing rotation/pivoting about axis **A-B**.

Referring now to FIG. 4, hub **240** also comprises bolt head **242**. As illustrated in FIG. 4, bolt head **242** is adapted to be engaged by rotational tool **350** so that curved needle **220** can be rotated about axis **A-B** (FIG 3) in both a clockwise and counterclockwise direction. Curved needle **220** is illustrated in a closed position. If curved needle **220** is rotated 180 degrees counter-clockwise, it would be an open position. When in the open position (NOT illustrated), no portion of curved needle **220** extends beyond outer surface **611** of wall **610**. When curved needle **220** is in the open position and bolt head **242** is rotated in a clockwise direction, curved needle **220** will rotate in a clockwise direction until it contacts stopper **230**. Once curved needle contacts stopper **230**, stopper **230** prevents curved needle from rotating any further in the clockwise direction.

In another embodiment, stopper **230** can be adapted so as to not interfere with the rotation of curved needle of **220** about axis **A-B**. In this embodiment, sleeve **250** can be adapted to act as a stopper if desired. Additionally, sleeve **250** can be sized so that the tight fit between cylindrical stub **241** and sleeve cavity **251** does not allow free rotation of curved needle about axis **A-B** without force being exerted by rotational tool **350**.

Clip assembly **200** is secured to wall **610** of anti-reflux prosthesis **400** through the use of teeth **215**, as is illustrated in FIG. 4.

Anti-reflux prosthesis **400** is inserted into an esophagus **30** with all of the curved needles **220** in an open position. In FIG 5 the curved needle **220** illustrated on the left is shown in the open position. When in the open position, curved needle **220** does not engage internal wall **31** and does not interfere with the insertion/placement of anti-reflux prosthesis **400** in esophagus **30**.

In operation, the anti-reflux prosthesis **400** is first positioned in the desired location within esophagus **30**, and then each curved needle **220** is pivoted about axis **A-B** from the open position to a closed position. The curved needle **220** illustrated on the right is shown in the closed position. As curved needle **220** is pivoted from the open position to the closed position, curved needle **220** pierces and engages internal wall **31**, securing anti-reflux prosthesis in place. Once secured to internal wall **31**, anti-reflux prosthesis **400** can be removed by pivoting all of the curved needles **220** back into the open position. All pivoting of curved

needle **220** within esophagus **30** can be accomplished with rotational tool **350** (FIG. 4) through the use of an endoscope.

In another method of using the present invention, anti-reflux prosthesis **400** is inserted and positioned within esophagus **30** with each curved needle **220** in the closed position. This closed orientation ensures that curved needle **220** does not prematurely pierce or cut internal wall **31** during insertion and positioning. Once inserted, each curved needle **220** will be rotated 360 degrees in the appropriate direction instead of 180 degrees.

Referring now to FIG. 6, hub **240** can be modified to be compatible with any type of rotational device. As illustrated, hub **240** can have a female socket **245** instead of a bolt head for facilitating pivoting of curved needle **220**. The female socket **245** can receive a male-ended rotational device rather than a female-ended device **350**.

While the invention has been described and illustrated in sufficient detail that those skilled in this art can readily make and use it, various alternatives, modifications, and improvements should become readily apparent without departing from the spirit and scope of the invention. Specifically, the clip body can be adapted to comprise a cavity formed within the clip body itself. In this embodiment, a sleeve is not necessary and the cylindrical stub of the hub will fit directly into this cavity to form a tight fit.

What is claimed is:

1. An apparatus to be inserted into a biological lumen having an internal wall, said apparatus comprising a curved needle pivotable about an axis between an open position and a closed position and adapted to pierce and engage said internal wall when pivoted from said open position to said closed position.

2. The apparatus of claim 1 wherein said curved needle is adapted to disengage said internal wall when pivoted from said closed position back to said open position.

3. The apparatus of claim 1 further comprising means to pivotally support said curved needle.

4. The apparatus of claim 3 wherein said means to pivotally connect said curved needle comprises a hub having a bottom, said bottom having a cylindrical stub adapted to tightly fit into a corresponding cavity on said apparatus.

5. The apparatus of claim 4 wherein said curved needle protrudes from a side wall of said hub.

6. The apparatus of claim 5 wherein said curved needle is substantially semi-circular shaped.

7. The apparatus of claim 4 wherein said hub comprises means to be engaged by a rotational tool.

8. The apparatus of claim 7 wherein said means to be engaged is a female socket or a bolt head.

9. The apparatus of claim 7 wherein said curved needle is semi-circular shaped.

10. The apparatus of claim 1 wherein said lumen is an esophagus and said apparatus is an anti-reflux device.

11. The apparatus of claim 1 further comprising a clip body to which said curved needle is pivotally connected.

12. The apparatus of claim 11 further comprising means to stop said curved needle from pivoting beyond said closed position when said curved needle is pivoted into said closed position from said open position.

13. The apparatus of claim 11 wherein said clip body comprises a cavity, said curved needle being pivotally connected to said clip body by a cylindrical stub extending from a bottom of a hub into said cavity on said clip body to form a tight fit.

14. The apparatus of claim 11 wherein said clip body is a rigid structure comprising a front plate, a back plate, and a top plate having a hole; wherein either or both of said front and back plates have one or more teeth; said apparatus further comprising a sleeve forming a sleeve cavity and positioned between said front and back plates so that said hole and said sleeve cavity are substantially aligned; and said curved needle being pivotally connected to said clip body by a cylindrical stub extending from a bottom of a hub, through said hole, and into said sleeve cavity to form a tight fit with said sleeve cavity.

15. The apparatus of claim 14 wherein said curved needle is substantially semi-circular shaped.

16. The apparatus of claim 15 wherein said curved needle protrudes from a side wall of said hub and said hub comprises means to be engaged by a rotational tool.

17. A method of securing an apparatus to an internal wall of a biological lumen comprising:

providing a pivotable curved needle having an open position and a closed position;

inserting said apparatus into said biological lumen; and

pivoting said curved needle about an axis to said closed position, thereby causing said curved needle to pierce and engage said internal wall.

18. The method of claim 17 wherein said curved needle is in said closed position during said insertion.

19. The method of claim 17 wherein said curved needle is in said open position during said insertion.

20. The method of claim 17 further comprising removing said apparatus by pivoting said curved needle about said axis from said closed position to said open position, thereby causing said curved needle to disengage from said internal wall.

21. The method of claim 17 wherein said lumen is an esophagus and said apparatus is an implantable anti-reflux device.

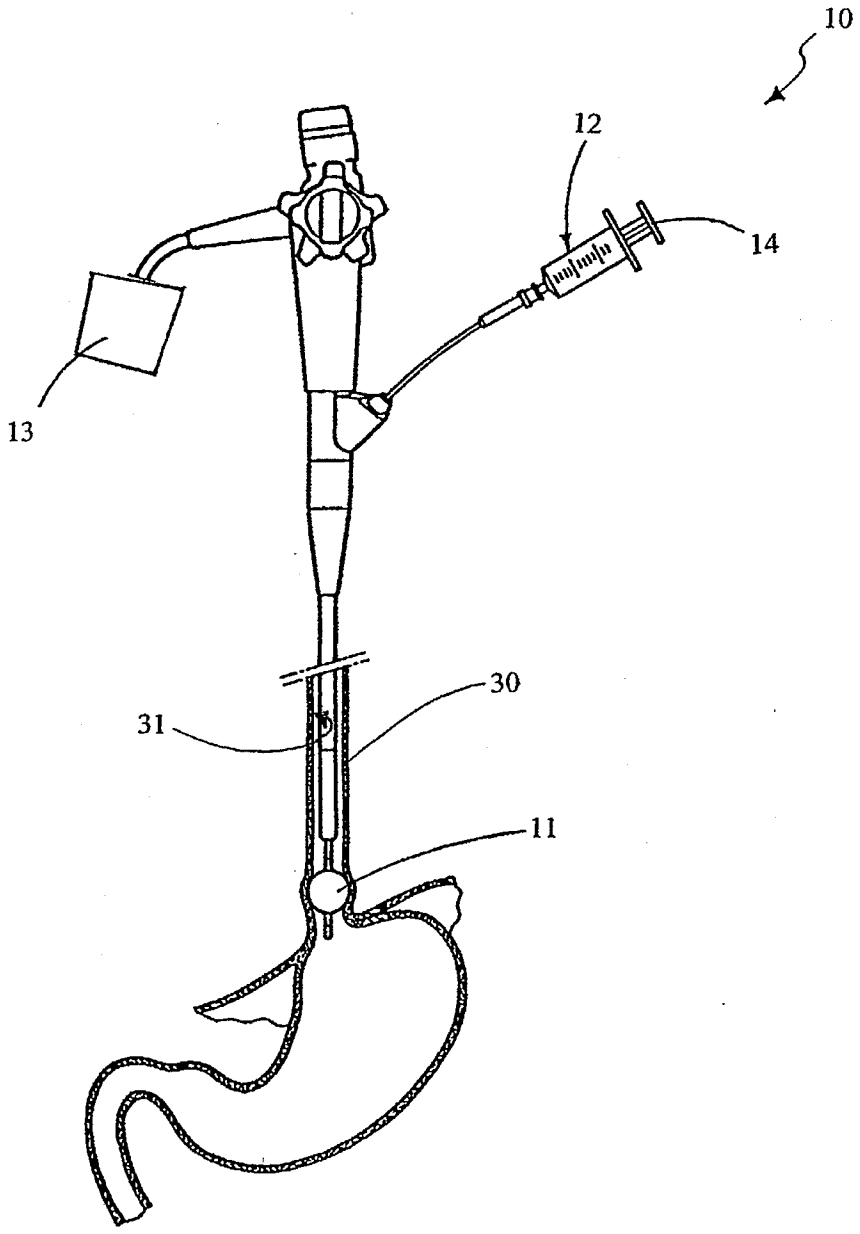


Fig. 1

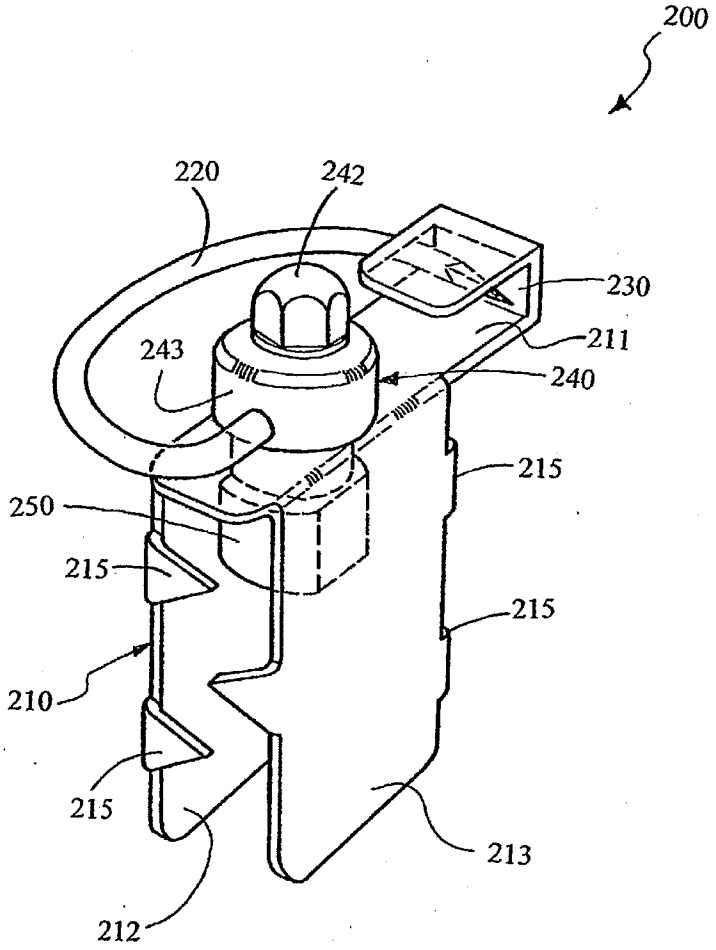
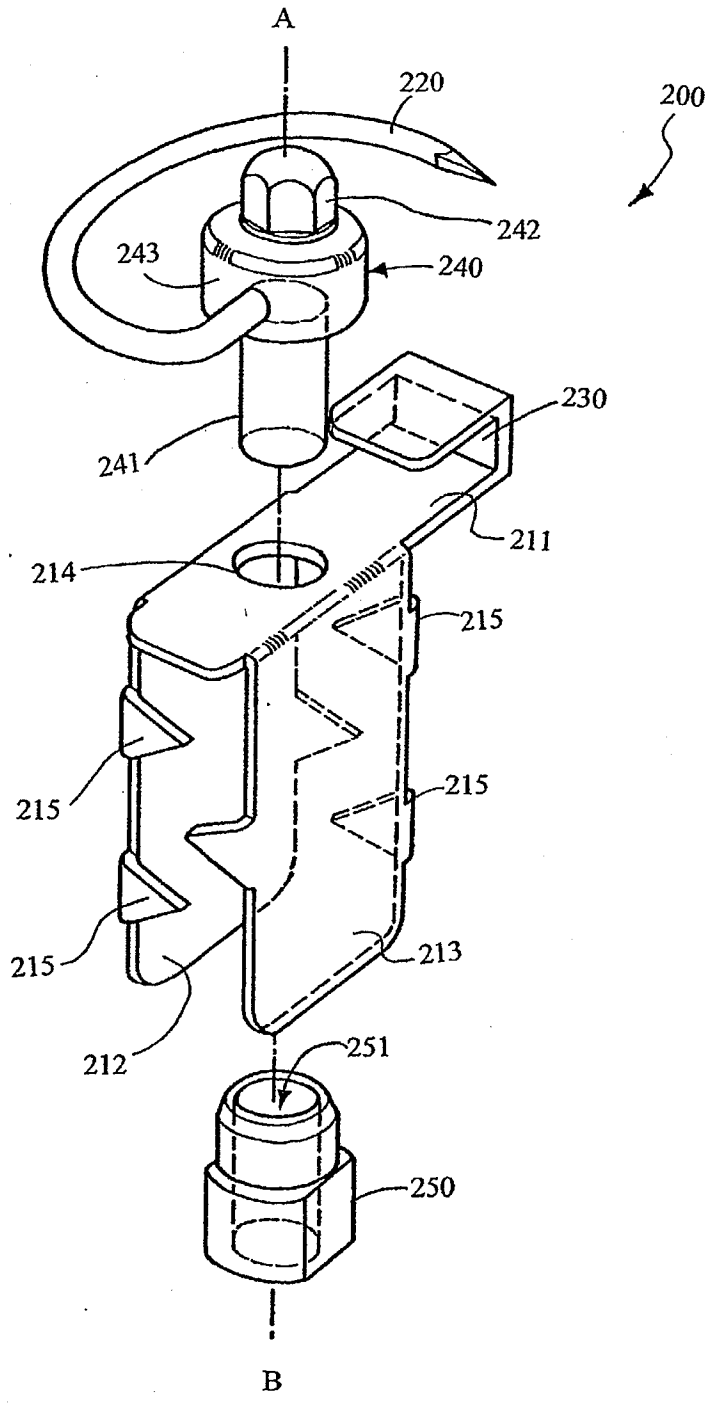


Fig. 2


A
220
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B

Fig. 3

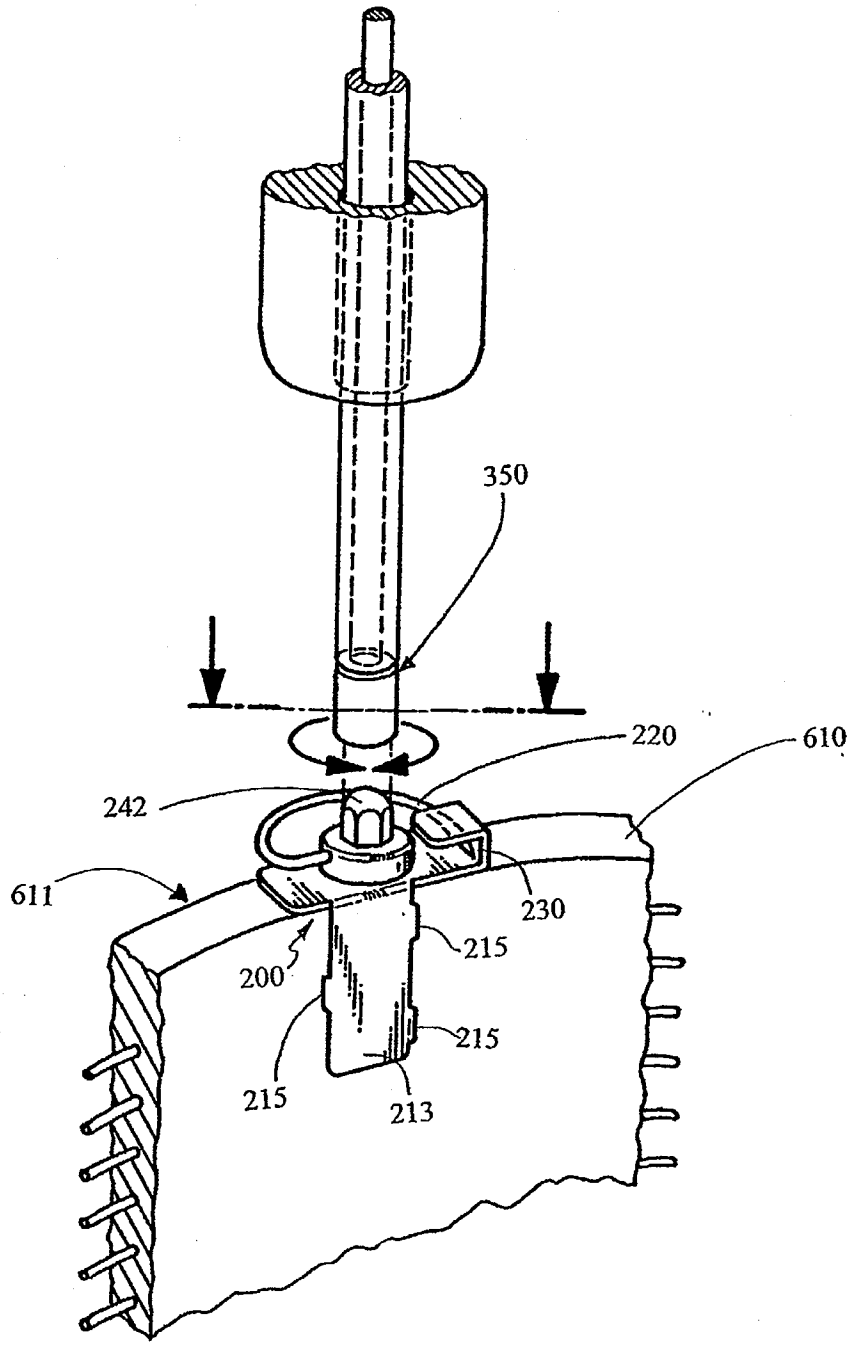

Fig. 4

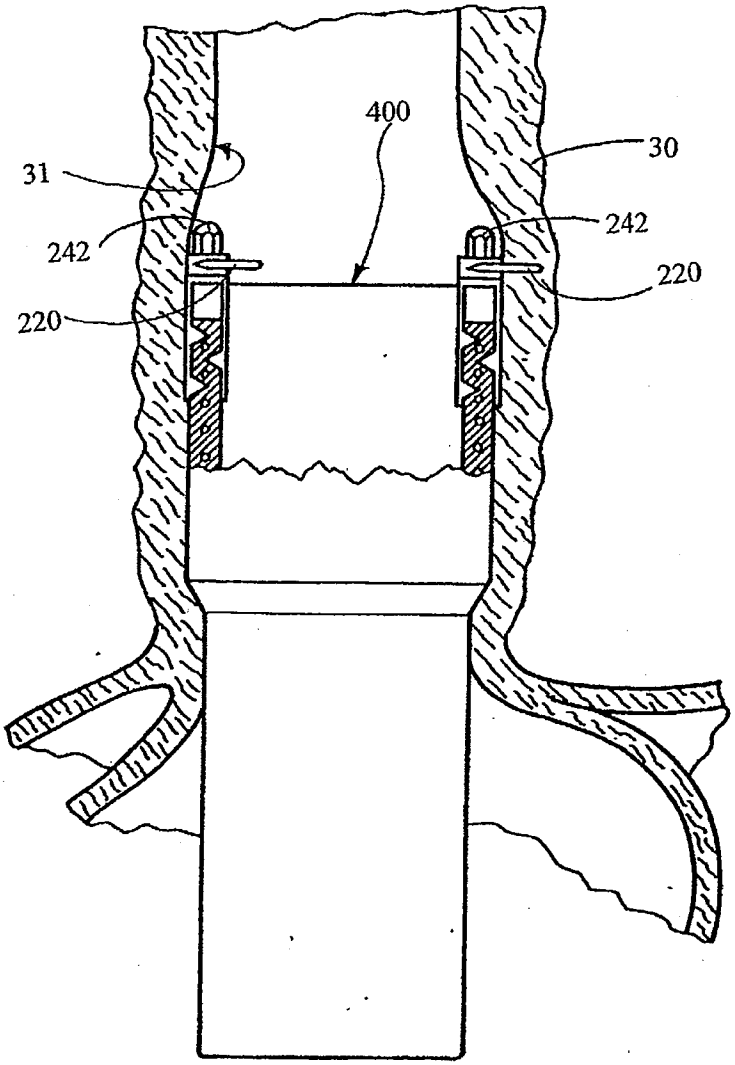

Fig. 5

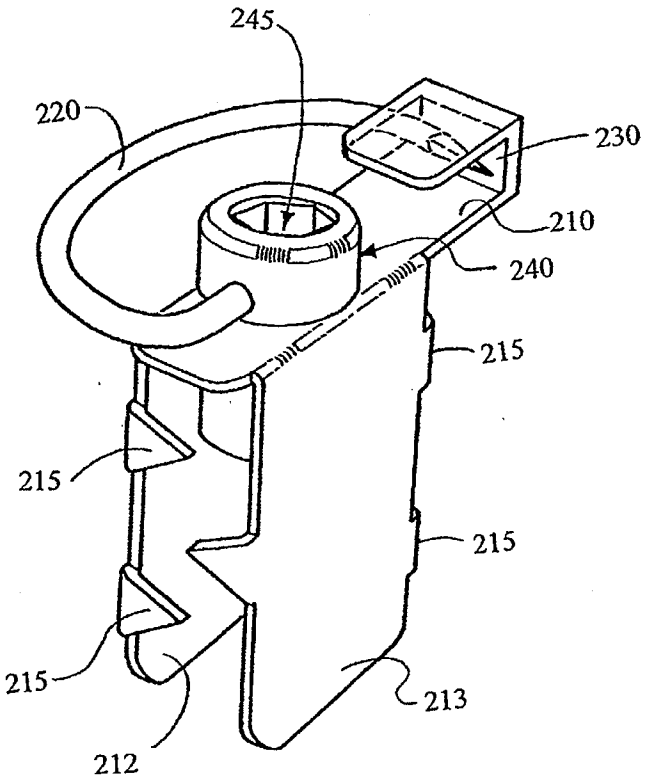

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/15731

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/04
US CL : 623/23.64

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/11.11, 23.64, 23.65; 600/037

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,254,642 B1 (TAYLOR) 03 July 2001, see entire document.	1-21
A	US 6,004,347 A (MCNAMARA ET AL) 21 December 1999, see entire document.	1-21
A	US 5,314,473 A (GODIN) 24 May 1994, see entire document.	1-21

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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